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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,126	10/28/2003	Richard L. Antrim	006401.00433	6117
22908 7590 03/12/2009 BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606				
EXAMINER				
HANLEY, SUSAN MARIE				
ART UNIT		PAPER NUMBER		
1651				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,126

Applicant(s)

ANTRIM ET AL.

Examiner

SUSAN HANLEY

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim 1-4 are pending and under examination.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 2/17/09.

NEW GROUNDS OF REJECTION

The following new grounds of rejection are made against claims 1-4.

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaper et al. (US 4,780,149; cited in the IDS filed 9/23/05) in light of Haynes (US 6,013,299) and Huang et al. (US 6,823,799).

Claim 1 is drawn to a method having the following steps for spraying maltose by providing a maltose-containing product and adding to it a dextrin to form a blended product wherein the dextrin enhances its susceptibility of said product to be spray-dried. The blended mixture is spray-dried. The dextrin is claimed as a product by process due to the “having been prepared” language. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

As stated by the MPEP 2113:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding “interfolded by interfusion” to limit structure of the claimed composite and noting that terms such as “welded,” “intermixed,” “ground in place,” “press fitted,” and “etched” are capable of construction as structural limitations.)

In the instant case, the steps for making the recited dextrin product require that the product resulting from the steps is a composition that is rich in dextrin, has at least on sugar

having a degree of polymerization less than 10 (from the beta amylase digestion of starch) and a reduced content of retrograded starch. This results from precipitation and filtration in the product-by-process method. The dextrin can be a beta-limit dextrin. Claim 3 further define the process insofar as the starch is also treated with alpha amylase. Claim 4 further comprises a physical step of treating starch with beta amylase.

Kaper discloses the preparation of a maltose/ β -limit dextrin composition by contacting starch with β -amylase, followed by α -amylase treatment, precipitation of the amylose by lowering the temperature of the enzyme-mixture and separation of the precipitate from the β -dextrin/maltose-containing solution by centrifugation or filtration. The enzyme-treatment decreases the viscosity of the hydrolysate (col. 2, lines 11-32 and column 3, lines 1-25 regarding the embodiment wherein the precipitated amylose is removed from the dextrin and maltose-containing solution). The maltose/dextrin product is then spray-dried. Kaper does not designate the precipitated amylose as retrograded. Haynes (US 6,013,299) teaches that retrograded amylose (starch) is prepared by decreasing the temperature of a starch dispersion to make a precipitate that is the retrograded amylose. The process is accelerated by amylase treatment (col. 4, lines 50-67). Kaper discloses that the DE of the maltose/ β -limit hydrozylate is about 5-30 and that the alpha amylase treatment results in a product wherein the DE of the starch hydrozylate is increased by no more than 3 units. Thus, the DE of the final hydrozylate by the treatment with both enzymes is 8-33 which corresponds to a DP range of 3 to 12.5 ($DE=100/DP$; Huang gives the DE:DP relationship at col. 4, lines 46-43) which overlaps the claimed DP range of less than 10.

Huang and Haynes are cited to show facts that were already known in the art at the time the invention was made.

Kaper teaches that the disclosed maltose/ β -limit dextrin composition is useful in food and pharmaceutical products and that β -limit dextrans can also be used as a carrier of dried liquids such as fruit juices, etc. (col. 3, lines 26-39).

Thus, the product of Kaper is a dextrin digestion product of alpha-amylase and beta-amylase, as required by the product by process that has a DP that overlaps the claims range. The retrograded amylose is precipitated and removed which decreases the viscosity of the enzyme-traded starch product, thus making it better suited for spray-drying. Instant claim 3 is also directed to product-by-process language wherein the starch "having been liquefied" with alpha-amylase prior to the beta-amylase treatment. The reversal of steps by Kaper is not critical product since the steps results in a maltose/dextrin product having a DP that overlaps the claims range.

The requirement of ultrafiltration in the product-by-process recitation in claim 1 also fails to distinguish the claimed dextrin product that of Kaper because the claimed ultrafiltration requires only the reduction of the precipitated retrograded amylose, not a specific reduction by percent. Thus, the product of Kaper, a spray-dried maltose/beta-limit dextrin that has a reduced amount of retrograded amylose having a DP that overlaps the claimed range of less than ten.

Once a product appearing to be substantially identical is found and a rejection under 35 USC 102/103 is made, the burden shifts to the applicant to show an unobvious difference. The MPEP 2113 states:

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is

claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal."

Therefore, Kaper discloses the claimed method steps of providing the spray-dried maltose-containing product. The dextrin is a beta-limit dextrin. Claim 4 is a method step that requires the digesting of starch with beta amylase, which is disclosed by Kaper. The claimed enriched dextrin is claimed as a product-by-process wherein the process results in a composition having a DP less than 10 and a reduced level of retrograded starch. Hence, a holding of anticipation/obviousness is therefore required.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boskovic et al. (US 5,124,162; cited in the Office Action mailed 7/3/07) in view of Tang et al. (US 5,854,487; cited in the last Office action) and Huang et al. (US 6,823,799).

Boskovic discloses an antioxidant-free, stable fixed flavor which is prepared by combining a flavor, maltose, maltodextrin and a film former to make a mixture and then spray-drying the mixture to form a dense product (abstract). Boskovic provides disclosure relating to the relative amounts of maltose and malto-dextrin, as well as the preferred DE range of 5-15 for

the latter (col. 6, lines 9-30) which corresponds to a DP range of 6.5 to 20 ($DE=100/DP$) which overlaps the claimed DP range of less than 10.

The step of instant claim 1 relating to providing an amount of dextrin to enhance the susceptibility of the maltose-containing product to be spray-dried is considered to be a mental step in the absence of any physical steps to determine this optimization. Hence, Boskovic meets these limitations because the disclosure of the desired relative amounts of maltose and maltodextrin are provided to optimize the spray-drying qualities of the mixture to form the desired dense product.

Boskovic does not disclose a maltodextrin carrier is prepared by treating starch with a beta-amylase wherein retrograded amylose is produced and at least some of the retrograded amylose is separated via ultrafiltration wherein the resulting product has a $DP < 10$; or the starch is liquefied with an alpha-amylase prior to beta-amylase treatment.

Tang discloses that it is desirable to employ nanofiltration to enzyme- or acid-hydrolyzates of starch to remove retrograded amylose and to obtain a low DE hydrolylate blend. The DE is in the range of 4 to 18 (col. 7, lines 1-10) which corresponds to a DP of 5.5 to 25 (Huang gives the DE:DP relationship at col. 4, lines 46-43) which overlaps the claimed range of less than 10. Such products are substantially retrograde-product free and have a very low viscosity. Low DE (DP) products that lack retrograded amylose are particularly suited for spray-drying (abstract and col. 3, lines 63-68 to col. 4, lines 1-13).

Huang is cited to show facts that were already known in the art at the time the invention was made.

Claim 1 is drawn to a method having the following steps for spraying maltose by providing a maltose-containing product and adding to it a dextrin to form a blended product wherein the dextrin enhances its susceptibility of said product to be spray-dried. The blended mixture is spray-dried. The dextrin is claimed as a product by process due to the "having been prepared" language. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps as stated by the MPEP 2113 *supra*. Thus, the malto-dextrin product of Tang meets the product-by-process part of claim 1 since the resulting product is a malto-dextrin having a DP in the range of 5.5 to 25 which overlaps the claimed range of less than 10 and wherein the content of retrograded amylose is reduced by filtration. The type of filtration does not bear on the patentability of the product since nanofiltration and ultrafiltration serve to remove retrograded amylose to produce a malto-dextrin having a reduced content of retrograded amylose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the malto-dextrin prepared by Tang as a carrier for spray-drying maltose containing products. The ordinary artisan would have been motivated to do so because Tang specifically recommends that hydrolyzed starch which have been subjected to retrograded amylose removal are very desirable for spray drying due to their very low viscosity. The ordinary artisan would have had a reasonable expectation that the method of producing a maltodextrin according Tang would suit the spray-drying method disclosed by Boskovic because it has reduced retrograded amylose content as well as a DP value that results in a viscosity desirable for spray-drying.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,670,155 in view of Kaper et al. (US 4,780,149; cited in the IDS filed 9/23/05) in light of Haynes (US 6,013,299) and Huang et al. (US 6,824,799).

The ‘155 patent is drawn to a method for producing a malto-dextrin composition by the same steps that are recited in the instant product-by-product portion of the instant claims.

The ‘155 patent does not disclose that the malto-dextrin product is spray-dried.

The disclosure by Kaper, Haynes and Huang is disclosed supra. Kaper discloses that the DE of the maltose/ β -limit hydrozylate is about 5-30 and that the alpha amylase treatment results in a product wherein the DE of the starch hydrozylate is increased by no more than 3 units. Thus, the DE of the final hydrozylate by the treatment with both enzymes is 8-33 which corresponds to

a DP range of 3 to 12.5 ($DE=100/DP$). As discussed supra, the method of Kaper results is a product that anticipates/is obvious over the product-by-process portion of instant claim 1. Kaper discloses that low DE (DP) malto-dextrin compositions having reduced retrograded amylose are suited for spray-drying .

It would have been obvious to one of ordinary skill in the art at the time the invention was made to spray-dry the product yielded by the method steps of claim 1-4 of the '155 patent. The ordinary artisan would have been motivated to do so because the method steps of '155 result in the product-by-process of the instant claims, e.g., the resulting products are identical. Hence, the properties of said resulting products are the same and both are amenable to spray-drying, as suggested by Kaper who makes the same product. The ordinary artisan would have had a reasonable expectation that said the product resulting from the steps of the '155 patent could be spray-dried because Kaper demonstrated that the same product produced by a different method is suitable for spray-drying.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Irene Marx/
Primary Examiner
Art Unit 1651